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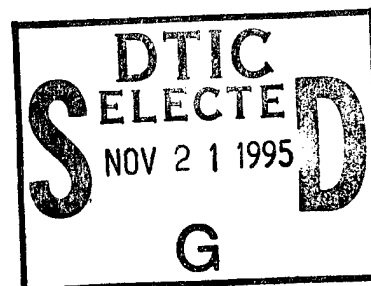
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13. ABSTRACT (Maximum 200 words) In 1985, the DoD started screening for antibody to human immunodeficiency virus (HIV). Once discharged from the Army, individuals previously followed, can become lost to follow-up, seeking medical care through VA, other military or private care facilities. "Lost to follow-up" is defined as a year passing since last clinical staging evaluation. Additionally, those confirmed as HIV-positive, but who have not received a clinical evaluation within 60 days of diagnosis date are considered lost to follow-up. The Medical Follow-up Agency (MFUA) of the Institute of Medicine contracted with the Army to help determine morbidity and mortality endpoints for those lost to follow-up, as defined above, for a study evaluating the natural history HIV-infection. VA, Army, Navy and Air Force hospitalization diagnoses were checked for morbidity considered as relevant disease staging endpoints. Mortality was established for beneficiaries seeking claims through the VA system, and death certificates obtained. A search of the National Death Index was conducted twice to determine any additional mortality experience. Morbidity and mortality endpoint data and death certificate copies were sent to the Army. Original contract work related to contacting of patients was not done, because of changes within the original Army scope of work that was in place when the contract started.				
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Diane J. Mundt 10/12/95
PI - Signature Date

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**Study of Post-Separation HIV-Positive Service Members
Lost to Follow-up
(U.S. Army Medical R&D contract DAMD17-91-Z-1040)**

Introduction

In October 1985, the Department of Defense began screening for the presence of antibody to human immunodeficiency virus (HIV). While HIV-infected servicemembers are on active duty, the Army health care system can maintain surveillance and clinical follow-up of these individuals. However, once discharged, they can become lost to follow-up, seeking medical care through VA, other military or private care facilities. An individual is considered "lost to follow-up" (LTF) when more than a year has passed since his or her last clinical staging evaluation. Additionally, those individuals confirmed as HIV-infected, but who have not received a clinical evaluation within 60 days of their diagnosis date are considered lost to follow-up.

As part of a larger Army study to evaluate the natural history of those who are identified as HIV-infected in the Army, the Medical Follow-up Agency (MFUA) agreed to assist in the determination of morbidity and mortality endpoints for those lost to follow-up, as defined above. For individuals seeking medical care outside of the Army system, but within the VA medical system, information on relevant hospitalization diagnoses were determined for morbidity considered as relevant disease staging endpoints. A similar check was made of the individual service branch (Army, Navy, Air Force) hospitalization data sources. Mortality was established for beneficiaries seeking claims through the VA system, and death certificates obtained. A search of the National Death Index was conducted twice to determine any additional mortality experience.

Morbidity and mortality endpoint data were sent to the Army, and death certificates, when available were obtained, coded, and copies forwarded to Army researchers. Original contract work related to contacting of patients was not done, because of changes within the original Army scope of work that was in place when the contract started.

Methods and Results

The contract identifies six work areas: records follow-up: mortality data; records follow-up: morbidity data; records follow-up: CDC AIDS registry; contact and follow-up of HCBs; data management: security and confidentiality; and data analysis and dissemination. Each of these areas will be discussed in turn.

Data had been received by the Medical Follow-up Agency (MFUA) from Walter Reed Army Institute of Research (WRAIR) at three time points from the beginning of the project through the fall of 1992. The first batch was received in November 1991, the second was received the beginning of 1992, and the third was received the end of October 1992. A preliminary review of the study subjects in these data batches received in the first year of the study, indicated that the potential study population varied between the batches. On 3 December 1992, a meeting with Army investigators established current status, progress and future plans of the study, as well as plans for formulation of the final data set. At this meeting, a decision was made to assemble a data set, as of the beginning of December 1992, that would constitute the beginning of the study cohort. Any service member in the database sent to MFUA on that date would be followed in the upcoming year. As the proposal agreement stated that follow-up would occur on new losses for a year after the study began, the decision to finalize the data set at the time of the meeting was consistent with the proposal.

The data were received by the MFUA on 7 December 1992, with a study population of 568 service members (547 men and 21 women) considered lost to follow-up.

The follow-up data determined for this group were given to the Army in December 1993; at that time, a second batch of servicemembers lost-to-follow-up was delivered to MFUA. Additionally, in September 1994, a third data file of lost to follow-up service members was sent to the MFUA. At this time, a separate data file was also received with individuals known to be deceased, but for whom no death certificate had been obtained. The MFUA sought to obtain death certificates for this latter group of individuals known to be dead.

A total of 891 unique individuals were followed to determine morbidity and mortality endpoints. In addition, the names of 532 unique individuals known to be deceased were sent to MFUA in order to obtain death certificates.

Records Follow-up: Mortality

In December 1991, the Medical Follow-up Agency (MFUA) contacted the Chief Benefits Director (CBD) of the Department of Veterans Affairs (VA), requesting access to VA benefits records. In January 1992, the CBD granted permission for the release to MFUA of identifying and claims file location information from the Beneficiary Identification and Records Locator Subsystem (BIRLS) and additional information in VA claims files on deceased veterans in the study.

In 1991, using one of the first lists of 623 names given to MFUA, a 10% sample of names (N=71) was chosen to check VA mortality ascertainment procedures.

Because the number of subjects in the sample was small, the 71 subjects chosen were traced one by one in the BIRLS system using a method referred to subsequently as TARGET, rather than sending the file to the VA in a single batch for off-line computer processing. The TARGETing was done not only because the one-by-one processing is faster for small samples, but also because the search algorithms for the one-by-one processing are more flexible than the batch processing algorithms, and the person doing the data input can customize the search if necessary to each case. In fact, TARGET searching was used for each of the three batches of data received, beginning December 1992. In addition to vital status, address and claims folder location information was determined from the BIRLS file. Vital status determination of the sample indicated that 87.3% were alive (presuming those without BIRLS folder locations to be alive), 9.9% were dead, and 2.8% had no record on BIRLS. Deceased subjects and those with folder locations accounted for 91.6% of the sample. Subjects with no BIRLS record or no folder location, who are harder to trace, were 8.4% of the sample. The results of this pilot study were sent to WRAIR on April 27, 1992.

Several methods were actually implemented to determine whether study subjects were deceased; these methods included the National Death Index, access to BIRLS, as described above, and review of individual VA claims folders. The number of deaths by year of death and source of mortality information is shown in Table 1. Each of the three methods used for determining mortality is described below.

NATIONAL DEATH INDEX (NDI)

An application to the National Death Index (NDI) was submitted on 16 December 1992, and covered a period of time from 1985-1991 for mortality searches. The application was approved, and the NDI search was done on 26 March 1993, with data received on those potential matches on 9 April 1993. A second search occurred on 28 September 1994, and covered the years 1985-1993. There was a small subset of individuals (n=50) who had died

in 1993 between NDI searches, and were therefore not included in either the 1993 or 1994 search.

For each search, the study subjects were compared by computer program for exact Social Security Number (SSN), name and date of birth match, with hierarchical matching criteria; an exact match occurred when SSN and full name were identical. A total of 82 death matches were identified through the NDI on the two searches. Therefore, of the 134 individuals who had been determined to have died between 1987 and 1993, 82 were found in NDI, 50 were not submitted in either NDI request, and 2 did not appear in the NDI matches. The NDI will lag necessarily about one calendar year behind BIRLS, in terms of completeness. Therefore, other methods might be more efficient for determining vital status, particularly for a population such as this with exceptionally high mortality, as described below.

TARGET ACCESS TO BIRLS

The first TARGETing of the batch of names received in December 1992 was completed in March of 1993. At that time, of the 568 eligible subjects, 555 were found in BIRLS, 9 records indicated a "sensitive" status, and 4 records were not found. Therefore, a total of 564 of 568 (99%) records located in this system. From this initial search, 61 study subjects were identified as deceased through BIRLS.

In August of 1993, the vital status of those previously assumed to be alive was re-checked in the BIRLS system. There were an additional 42 LTF found to be deceased through BIRLS at this time. It was therefore apparent that additional periodic checks of the BIRLS records were necessary to update the mortality status of this cohort.

For individuals received in the January 1994 batch of lost to follow-up, the names were submitted to TARGET in January, April and July of 1994. Of the 569 eligible subjects, 558 were found in BIRLS, 10 records indicated a "sensitive" status, and 1 record had no status. From the TARGET searches on this batch, a total of 52 study subjects were identified as deceased through BIRLS.

For individuals received in September 1994, names were TARGETed twice. A total of 212 individuals from the three batches were identified as deceased through BIRLS.

CLAIMS FOLDERS

Originally, a request was sent to the folder location indicated on the TARGET search to obtain 115 folders for service members with no address information available through TARGETing. In the process of reviewing the folders, two things became apparent: 1) in some instances, recent deaths had not been posted in the BIRLS, as a death certificate was in the folders for a person not previously known to us to be deceased; and 2) it appeared that there was information available in some of the records on staging and disease development that could be used to update staging, when veterans applied for disability and received a VA disability assessment examination.

Therefore, a decision was made to request folders for all individuals who had been found in the first batch (n=555) in order to verify mortality status, if possible, and to abstract any medical information (described below in further detail). Beginning in June 1993, folders were requested for all individuals in the December 1992 data batch, in order to supplement other described methods of obtaining mortality status and medical information.

For subsequent batches of lost service members received by MFUA, folders were requested for deceased individuals only to obtain death certificates. For those determined

through BIRLS to be deceased, but with no death certificate in the claims folder, repeated requests for folders were made, over the study period.

Requesting folders to obtain death certificates was the primary action on the data file received in September 1994 with names of those known to be deceased.

DEATH CERTIFICATE CODING

A total of 252 individuals were identified as deceased through the various approaches described above. Death certificates were obtained for 140 of the 195 deceased individuals with folders available (72%). Death certificates were coded by an experienced nosologist.

Records Follow-up: Morbidity data

Morbidity information relevant to the staging of HIV infection and disease progression was obtained from data on VA and service branch hospitalizations, through SSN matches. When a match was available, the initial data included all hospitalizations, whether HIV-related or not, as well as hospitalization occurrences at any point in time. Since the purpose of the follow-up activity is to identify additional information not previously available to the Army researchers, only those hospitalization and examination occurrences after the date last seen by the Army were included as morbidity endpoints. Additional morbidity data were also obtained from the VA claim folders. A list of "critical diagnoses" (Table 2) was developed to be consistent with the Army diagnostic codes that were being used to further stage patients.

To gain access to VA medical records, MFUA drafted a letter which was initially discussed and was reviewed by VA medical administration staff. After revision, the letter was sent to WRAIR for signature, and formal request was made of Dr. James Holsinger, Chief Medical Director (CMD) of the VA. The CMD granted access to the VA's automated hospital

discharge file (the Patient Treatment File, PTF) and medical records in a letter dated 10 April 1992.

At the December 1992 meeting, a decision was made with the Army investigators as to which data entries from the military and VA hospitalization tapes would be useful for their research purposes. From the VA, the Patient Treatment Files (PTF) data would be obtained; similar data are available from the Army Individual Patient Data System (IPDS), Navy and Air Force. Names of contact persons for obtaining data from the service branches were also obtained at this time.

PATIENT TREATMENT FILE (PTF)

Information on hospitalizations occurring between 1985 and 1993 at VA medical centers was obtained from the PTF data, up to the point when the request was made on 11 March 1993; data were received on 26 May 1993. Of the 568 in the first batch of names sent, 198 (35%) had at least one hospitalization in a VA facility at any time. Approximately 46% of these hospitalizations (n=91) were after the date last seen by the Army, for a "critical diagnosis;" this represents additional information from PTF which can be used for staging on approximately 16% of this study batch. A second request for PTF matches of later batches of names received occurred in March, 1995. These results were submitted to the Army researchers, but no analyses were conducted on these data.

ARMY - INDIVIDUAL PATIENT DATA SYSTEM (IPDS)

Information on hospitalizations within Army medical centers was available from the IPDS. Permission for access to these data was requested on 14 January 1993; data were requested on 5 March 1993. Data were received by the MFUA on 5 May 1993 in 2 sections, as the data collection system had been redesigned. However, comparable data could be obtained from both data sources. As with the PTF data, hospitalizations for critical diagnoses

occurring after the date last seen were noted as potentially contributing to staging information.

A total of 558 of 568 matched the Army data files for ANY hospitalization. Only 16% of the 558 were for critical diagnoses after the date last seen. However, this (N=92) group represents a sub-group of the data set which could have been identified by the Army researchers, as these data are available to the WRAIR researchers, as well. A printout of available information on these individuals was forwarded to the Army researchers.

The search of the IPDS system did not occur for subsequent batches of names received, because the Army investigators determined that they should be able to obtain and update this information.

AIR FORCE HOSPITALIZATION DATA

Permission to access hospitalization data from the Air Force was requested on 16 December 1992, the data were requested on 5 March 1993, and received on 26 April 1993. A total of 31 hospitalization matches with the study population was available. Of the 31, only 3 matches had data for critical diagnoses for staging occurring after the date last seen. This represents additional information from the Air Force on less than one percent of the study subjects. No further requests for hospitalization data were made from the Air Force for subsequent batches of names received from WRAIR.

NAVY HOSPITALIZATION DATA

Permission to access hospitalization data from the Navy was requested on 16 December 1992, the data were requested on 25 March 1993, and received on 13 August 1993. We had considerable difficulty obtaining the data from the Navy, primarily because of concerns on their part with respect to the sensitive nature of the data. When the data were finally received by MFUA, there were only 4 matches for any hospitalization of study subjects, and only one of the matches was a study subject with an updated, staging critical diagnosis. No further

requests for hospitalization data were made from the Navy for subsequent batches of names received from WRAIR.

VETERANS' ADMINISTRATION (VA) MEDICAL RECORDS

Medical records of PTF hospitalizations for Stage 6 and cancer diagnoses occurring after the date last seen were requested in 1994. These records were requested for individuals identified in the December 1992 batch and for some of the names from the January 1994 batch. Medical records for 85 individuals in the December 1992 batch were requested; records for 66 were received. The medical records for Stage 6 or neoplasm diagnoses were abstracted, representing a total of 91 diagnoses, which included multiple diagnoses for some individuals. For approximately 30% (37 of 91 diagnoses) of the total Stage 6 or neoplasm diagnoses, the medical record indicated that there was a previous history of admission for the same diagnosis. That is, this was not, in fact, the first occurrence of a staging or cancer diagnosis. In addition, the process of requesting and obtaining information relevant to a specific diagnosis was both cumbersome and complicated. Medical records are available from local VA medical centers by admission date, therefore, information included for a diagnosis of interest on a specific admission date had to be requested. Even when requests were made for information from these specific dates, the information received varied greatly by medical center. For example, some hospitals sent only the admission of interest, some sent the whole patient history and some sent information on several admission dates, but not the one of interest. Also, the information provided in the medical summaries and lab reports varied not only by place of admission, but by different attending medical personnel. Thus, the quality of information received was not consistent, and should be used cautiously in determining patient staging progress. Since the initial purpose for abstracting these medical records was to obtain additional information relevant to the initial Stage 6 diagnosis for an individual, other mechanisms may need to be considered for this purpose. Some findings relevant to this

process are given in Table 3 flow chart. No additional requests for medical records were made for names sent in the September 1994 batch.

CLAIMS FOLDERS

As mentioned above, folders were requested for the first batch of study participants who had been located through BIRLS, as the TARGET results indicates where an individual's folder is located. A total of 357 of the 555 potentially available folders were received by the end of September 1993; this represents 64% of the study population. Quantity and quality of medical information varied considerably. Some medical record information was available in the folder if copies from other facilities had been requested by the VA. There was also information available in some folders from the disability rating examinations conducted by the VA, generally on an outpatient basis. Whenever possible, information on critical staging diagnoses, T-cell counts and Walter Reed staging was abstracted. This information was added to the data submitted to the Army.

Following discussions with WRAIR collaborators, folders were not requested for subsequent batches for the purpose of obtaining medical information because this was determined not to be a useful source of staging information for the period after the date the patient was last seen by the Army.

Record Follow-up: CDC AIDS Registry

As part of the original proposal, an attempt was to be made to obtain additional staging information on the positive HIV population from the CDC AIDS registry. On 5 February 1993, a conversation with Dr. John Ward at CDC who is in charge of the AIDS registry, resulted in the decision to not pursue this path to additional information. Dr. Ward was cooperative in providing us with the information on what would potentially be required, if we

wanted access to this registry, which contained in February 260,000 persons with AIDS per CDC definition. First, a combination of letters (SOUNDEX), date of birth and gender are used to indicate a registrant. The SOUNDEX is not specific, and would lead to very poor matching. Secondly, the access to these names is extremely tightly guarded. The state or local health departments actually have the names of the registry participants, and Dr. Ward said that there are extremely limited ways to gain information from the states. The states cooperate with CDC only because protection to the participants is guaranteed. Permission to obtain any information, including poorly matched information, would be required from the individual states. This was not encouraging as a method for tracking the patient population. Therefore, following discussions with the Army researchers, no further action will be taken to obtain information from the CDC.

Contact and Follow-up of HCBs

Because the personal contact of those LTF was included in the original contract, initial steps were made to implement this process. Before attempting to contact the LTF, it was necessary to obtain approval from the National Academy of Sciences' Committee to Review Human Subjects (IRB). MFUA, in collaboration with WRAIR, drafted a subject contact letter with postcard response, a volunteer agreement affidavit (DA FORM 5303-R), and two versions of a clinical interview form: self-administered and nurse-administered. These documents were reviewed by personnel in the Institute of Medicine's AIDS program. At its 31 March 1992 meeting, the Academy's IRB approved the MFUA proposal.

As a second step in the pilot study discussed earlier, addresses were sought for the 10% sample, minus the seven deaths and the two "no records." For the 62 individuals in this second step, there were 41 records with a current address on record and 21 records without an

address. Thus, about two-thirds of the sample found via VA records was presumed to be adequately located.

However, interview and re-examination of HIV patients LTF was not part of the revised study plan. This decision was made by the Army collaborators and relayed to the MFUA in April 1993. Therefore, no further activities related to this aspect of the study are reported.

NIOSH CONTACT

With the original contract anticipating contact of study participants, and the need for further address tracing, a request was made to the National Institute for Occupational Safety and Health (NIOSH) for access to Internal Revenue Service address files. Through a specific legislative agreement, NIOSH reviews all such requests for studies of veterans and, if approved, forwards the requests to IRS. MFUA's request was reviewed by NIOSH personnel and was rejected. Typically, outside requests involve studies of military veterans who have been exposed to hazards in military service, and according to NIOSH personnel, our request did not fit these guidelines.

Therefore, in December 1992, MAJ Pete Peterson at the Pentagon was contacted regarding the line of duty connection for HIV positive service members. Although there is no formal documentation which specifically states that HIV-related illness is line of duty (LOD) connected, if a person who tests negative before entering the service is diagnosed with HIV "while wearing a uniform," the diagnosis is determined by presumption to be LOD connected. Regulations which pertain to HIV positive individuals in the service were sent to the MFUA, and included in a second request sent to NIOSH 21 December 1992. By March, no action had been determined, and in fact, NIOSH claimed never to have seen the re-submitted request. Therefore, on 23 March 1993, a second request was sent to ask for information from the IRS.

In June of 1993, access was refused. More specifics pertaining to reasons for refusal were obtained, and a request was drafted for signature by the Director, WRAIR on 20 July 1993. The request for this signature was denied on advice of SGRD-JA. Therefore, there was no further plan to pursue contact with NIOSH to obtain addresses from the IRS.

Data Management: security and confidentiality

MFUA has its own dedicated file server. No other Institute of Medicine divisions are given access to this machine, and access to the LTF data files is thereby strictly controlled.

Data were maintained in Paradox files within the MFUA, with password-protected access to the databases. A master file with the tracking information pertaining to the individuals in the data set was maintained and updated as new information was available. Data are also available from the medical records abstraction and the matches from the hospitalization data. Merged data sets were sent to the Army, in ASCII format, for updating their records.

As part of the data management, an anomaly was discovered in the processing of the folder data. It appears that five individuals had no diagnosis of being HIV positive, or any other indicator of HIV positive status. Information that was available on these 5 individuals was sent to Army researchers.

Data Analysis and Dissemination

Preliminary analysis of the data were included with previous data sets sent to the Army researchers. Tables from this preliminary analysis were also included in previous progress reports.

The dissemination of this project consists of the deliverables sent to the Army researchers. Copies are not included here, because of the inclusion in the data of identifier information. The deliverables for this project include: copies of updated data files with relevant morbidity and mortality endpoints, copies of death certificates obtained, and a data file with the codes from the nosologist. These items were sent to MAJ Mark Rubertone, WRAIR.

Conclusions

A total of 891 individuals were followed for morbidity and mortality over 3 years. The primary contribution that has been made to the ongoing study by the Army of the natural history of HIV infection is the determination of mortality, not otherwise known, and obtaining a death certificate to document cause of death. Morbidity endpoints were less precise and of potentially limited value.

TABLE 1. NUMBER OF DEATHS BY YEAR AND SOURCE OF MORTALITY

	TARGET	NDI	FOLDER	TOTAL
1987	1	1		2
1988	2			2
1989	1			1
1990	-			0
1991	10			10
1992	35		1	36
1993	63	6	14	83
1994	78		9	87
1995	22			22
TOTAL	212	7	24	243

TABLE 2.**CRITICAL DIAGNOSTIC CODES UTILIZED FOR STAGES 5 AND 6**

CODE	NAME	STAGE
112.0	Oral candidiasis	5
007.2	Cryptosporidiosis, isosporidiosis	6
012-018	Extrapulmonary tuberculosis	6
031 (ALL)	Atypical mycobacteriosis	6
031.0	MAI	6
054 (ALL)	Herpes simplex	6
078.5	Cytomegalovirus	6
112.5	Esophageal candidiasis	6
115 (ALL)	Histoplasmosis	6
117.5	Cryptococcosis	6
117.9	Disseminated endemic mycosis	6
130 (ALL)	Toxoplasmosis	6
136.3	Pneumocystis carinii pneumonia	6

TABLE 3. PREVIOUS HISTORY (YES/NO) OF STAGE 6 DIAGNOSIS INDICATED IN THE MEDICAL RECORD FOR INDIVIDUALS WITH CRITICAL DIAGNOSIS IDENTIFIED IN PTF

